

**REMARKS**

Claims 41, 43-45, 47, 52-55 and 68 are currently pending. The Examiner has kindly withdrawn the previous rejections related to enablement and indefiniteness in conjunction with a specification objection, but has asserted a new written description/new matter rejection as follows:

- I. Claims 41, 43, 47 and 52-54 are rejected under 35 U.S.C. § 112 ¶ 1 as allegedly failing to comply with the written description requirement.
- II. Claims 44, 45, 55 and 68 are drawn to non-elected species or groups and must be canceled.
- III. Claim 41 is objected to for informalities.

**I. There Is Sufficient Written Description For The Claimed Embodiment**

The Examiner concludes that:

... the newly claimed method is not supported by the specification and the amendments constitute new matter.

*Office Action pg 7*, by specifically arguing that:

The specification only supports that comparison of cells contacted with or without protease inhibitors and the effects of these inhibitors have on the replication of the same virus, not the comparison of a non-plus stranded RNA virus to a coronavirus.

*Office Action pg 6*. The Applicants disagree and point out that the Examiner has admitted that “Claim 41 previously recited ... is supported in the specification”. *Office Action pg 3 bridging pg 4*. Notably, previous Claim 41 was not limited to “the effects of these inhibitors have on the replication of the same virus”. In fact, previous Claim 41 provided a broader basis for directly comparing a non-plus virus replication with a plus virus replication. The “no protease” inhibitor control was merely used as a means for discovering the differential impact of the inhibition, but

is not essential once the disarray is made. The point is that a direct virus-to-virus comparison was (and is) contemplated by the presently claimed embodiment and has proper written description support in the specification.

The Applicants' amendment in the previous response simply exemplified "a plus strand virus" as "a coronavirus":

The invention also relates to reducing infection with plus strand RNA viruses such as SARS-coronavirus.

*Applicant's Specification, pg 1ln 12-13.* Further, a direct virus-to-virus comparison is specifically contemplated:

In one embodiment, the invention provides compositions and methods for reducing infection with SARS-coronavirus, without substantially reducing infection with other respiratory viruses.

*Applicants' Specification, pg 84 ln 26-28.* Consequently, the Applicants' specification does support the comparison of a non-plus strand virus replication to a plus strand virus replication.

The Applicants' have interpreted the Examiner's argument as premised upon the assumption that the absence of a protease inhibitor (which was used as a control) with a plus strand virus (i.e., for example, a SARS-coronavirus) is essential to practice the invention. The Applicants respectfully submit that the Examiner may have overlooked the meaning of the data presented in Table 5. This data provides a reference point to exemplify the effectiveness of using a SARS-coronavirus in the presence of a protease inhibitor as an effective comparator virus. The "no protease inhibitor" control allowed one to see the background and to ensure that the virus-to-virus comparison is legitimate. Once this finding was made, it is clear that treating coronavirus with the inhibitor is desirable in order to inhibit replication. The Applicants teach that a routine assay using SARS-coronavirus without a protease inhibitor, simply as a known and predictable control, would be highly dangerous for the practicing personnel:

These methods are useful, where it is desirable to reduce exposure of personnel to SARS-coronavirus in clinical virology laboratories that routinely screen clinical specimen for respiratory pathogens ... other than SARS-coronavirus.

*Applicant's Specification pg 22 ln 1-4.* Clearly, the Applicants' have not provided any suggestion that replicating a coronavirus in the absence of a protease inhibitor is essential. Quite the contrary. The Applicants' specification teaches that is it undesirable to perform routine clinical testing where a coronavirus sample is performed in the absence of a protease inhibitor.

The Applicants have provided sufficient teaching to one having ordinary skill in the art that a protease inhibitor is a highly effective inhibitor of SARS-coronavirus:

In an exemplary 16 hour bio-assay, the protease inhibitor E64d inhibited the replication of human coronavirus 229E by 100% at concentrations of 32 µg/ml to 2 µg/ml. 90% inhibition was obtained with E64D concentrations of 1 µg/ml and 0.5 µg/ml.

*Applicants' Specification, pg. 102, ln 20-22 [emphasis added].* As a result of the this highly effective inhibition, it is clearly not necessary to perform this control sample in every SARS-coronavirus screen. Consequently, one having ordinary skill in the art has been provided with sufficient written description to practice the claimed embodiment without replicating coronavirus in the absence of a protease inhibitor.

The Examiner is respectfully requested to withdraw the present rejection.

## **II. Claims 44 and 45 Should Not Be Canceled**

The Examiner states that:

This application contains claims 44, 45, 55 and 68 drawn to an invention and species nonelected without traverse in the reply filed on April 30, 2008. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

*Office Action pg 2.* The Applicants respectfully disagree and submit that the proper MPEP section defining elections without traverse is § 821.02. This MPEP section does not specifically state that nonelected claims must be canceled under any circumstances, especially species elections. However, § 821.02 states that the Examiner may cancel non-elected inventions when elected claims are in condition for allowance, but claims containing species elections to the elected claims are specifically excluded:

... when the application is otherwise ready for allowance, the claims to the nonelected invention, except for claims directed to nonelected species and nonelected inventions eligible for rejoinder, may be canceled by an examiner's amendment, and the application passed to issue.

*MPEP § 821.02. After Election Without Traverse* [emphasis added]. In the present case, amended Claim 41 is on the record and incorporates a 'not a plus virus' Markush group including, but not limited to, parainfluenza virus and adenovirus species from the now canceled Claim 42. Claims 44 and 45 are proper dependent claims relating to this Markush group.

Nonetheless, the status of Claims 55, and 68 have been changed from Withdrawn to Canceled as drawn to a non-elected Restriction Group without traverse. The Examiner is respectfully requested to reconsider the cancellation of Claims 44 and 45.

### **III. Claim 41 Is Not Objectionable**

The Examiner states that:

Claim 41 is objected to because of ... informalities: ...

*Office Action pg 7.* The Applicants disagree. Nonetheless, without acquiescing to the Examiner's argument but to further the prosecution, and hereby expressly reserving the right to prosecute the original (or similar) claims, Applicants have amended Claim 41 to delete a duplicate "of" and a duplicate "virus". This amendment is made not to acquiesce to the Examiner's argument but only to further the Applicants' business interests, better define one embodiment and expedite the prosecution of this application.

**CONCLUSION**

The Applicants believe that the arguments and claim amendments set forth above traverse the Examiner's rejections and, therefore, request that all grounds for rejection be withdrawn for the reasons set above. Should the Examiner believe that a telephone interview would aid in the prosecution of this application, the Applicants encourage the Examiner to call the undersigned collect at 781-828-9870.

Dated: May 4, 2009



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